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10/019,586

12/20/2001

Vanessa Chisholm

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

01/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/019,586

Applicant(s)

CHISHOLM ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 113-127, 129, 130, 132-137, 140-160, 163 and 164 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 113-127, 129, 130, 132-137, 140-151, 163 and 164 is/are rejected.
- 7) ☒ Claim(s) 152-160 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/1/07, 8/7/07, 7/3/06, 2/6/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **Detailed Action**

#### **Improper Multiple Dependent Claims**

Claims 152-160 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from other claims in the alternative only and cannot depend from any other multiple dependent claims. Specifically, claim 152 does not refer to other claims in the alternative only and multiple dependent claim 158 depends from other claims which include another multiple dependent claim (152). Claims 153-157 and 159-160 are also objected to as they depend from these improper multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 152-160 have not been further treated on the merits.

The previous examiner should not have examined these claims as they are not drafted in accordance with acceptable multiple dependent claims practice. Once the claims are amended to comply with acceptable claim drafting practice, the claims will be examined.

It is noted that new grounds of rejection under Obviousness Type Double Patenting are applied as a result of applicants' actions in filing new applications 11/535,038 and 11/535,003 which claim subject matter not patentably distinct from the subject matter instantly claimed.

#### **35 USC 102 Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 151, 163 and 164 stand rejected under 35 U.S.C. 102(b) as being anticipated by Tan et al.

This rejection is maintained for reasons of record in the previous Office Action (mailed 9/12/05) and for reasons outlined below. The rejection against claims 112, 143-146, 161-162 is withdrawn as a result of applicants' amendment filed 11/1/07.

Applicants' arguments, as they pertain to the claims which still stand rejected, are as follows. Applicants dispute the previous examiner's interpretation of the term "operably linked" in the context of a promoter operably linked to a coding sequence. Applicants argue that the term is defined in the specification and applicants assert that a promoter that is "operably linked" to a coding sequence acts in cis to control or modulate the transcription of the linked sequence. Accordingly, applicants assert that the term "operably linked" cannot encompass "any combination/positioning of the components on the vector, as long as the components function in their intended manner", as stated by the Examiner in the previous Office Action.

Applicant's arguments filed 11/1/07 have been fully considered but they are not persuasive. The definition of "operably linked" in the specification is as broad as the previous examiner asserts. The portion of the specification highlighted by applicants which applicants assert explicitly defines and restricts the meaning of the term begins

with the phrase "For example". Clearly, applicants broadly define the meaning of the term "operably linked" and follow this definition by presenting **one example** of what is meant by the term and encompassed by the terminology. A fair reading of the portion of the specification dealing with the definition of the term "operably linked" would indicate that "operably linked" is broadly defined as asserted by the previous examiner and the "example" recited in the specification, and referred to by applicants, is not meant to be limiting.

Applicants assert that a prima facie case of anticipation has not been met because the claims, as amended, recite that the desired product comprises a polypeptide and because the VA1 gene present in the Tan et al. vector does not encode a polypeptide. Applicants assert that the examiner has not advanced any basis in fact or technical reasoning that the expression of the GFP and amplifiable marker are indicative of the cell also expressing VA1. Applicants disagree that the DHFR-GFP dicistronic vector (GFP mobilized into pED-MTXr) inherently discloses an IRES element because Kaufman states that the EMC is a putative IRES and that the examiner has not demonstrated that the EMC virus leader constitutes an IRES.

Applicants' arguments have been considered but are not persuasive. The desired product which can be expressed is not just VA1 but Tan et al. notes that the disclosed vectors can be used to express sequences encoding "therapeutic proteins" such as methioninase which can be expressed as fusions with GFP or independently using the dicistronic expression system (column 5, lines 4-18). Since the sequence encoding the protein of interest can be fused to the GFP, it must be expressed with the

GFP and the design of the vectors taught by Tan et al. teach an expression cassette comprising promoters and an IRES element which is designed to express the GFP, protein of interest and amplifiable marker and hence a cell expressing the GFP and amplifiable marker would also express the protein of interest.

With regard to the EMC virus leader not constituting a IRES, it is noted that the prior art teaches that the EMC virus leader comprises a well known IRES element of approximately 450 nucleotides (See for example, Hoffman et al., J. Virol., 1995, Vol. 60, No. 7, pp. 4399-4406) which is encompassed within the EMC viral leader (nucleotides 260-827, see Fig. 1 of the Kaufman et al. reference) used in the Tan et al. vector. Indeed, the EMC viral leader IRES element is one of the most well studied IRES elements in the literature.

For the reasons recited above and for reasons of record, the rejection is maintained.

### **Obviousness Type Double Patenting Rejections**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 113-127, 129-130, 132-137, 140-151 and 163-164 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of copending Application No. 11/535,038 (hereafter the '038 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite polynucleotides comprising the same components (i.e. amplifiable selectable gene, GFP gene, sequence encoding a desired product with the sequence encoding the desired product operably linked to either the amplifiable selectable gene or to the GFP gene, a promoter, one or two introns, IRES element, etc.), with the components positioned in the same orientation. The claims in the '038 application recite a polynucleotide comprising the aforementioned elements while the instant claims recite a vector comprising the same elements; however, the purpose of the polynucleotides is to express a desired gene of interest, i.e. use as a expression vector. Both sets of claims also recite host cells comprising said polynucleotides and methods of using the polynucleotides to produce the protein of interest.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 113-127, 129-130, 132-137, 140-151 and 163-164 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of copending Application No. 11/535,003. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite polynucleotides comprising the same components (i.e. amplifiable selectable gene, GFP gene, sequence encoding a desired product with the sequence encoding the desired product operably linked to either the amplifiable selectable gene or to the GFP gene, a promoter, one or two introns, IRES element, etc.), with the components positioned in the same orientation. The claims in the '038 application recite a polynucleotide comprising the aforementioned elements while the instant claims recite a vector comprising the same elements; however, the purpose of the polynucleotides is to express a desired gene of interest, i.e. use as a expression vector. Both sets of claims also recite host cells comprising said polynucleotides and methods of using the polynucleotides to produce the protein of interest.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims -127, 129-130, 132-137, 140-151 and 163-164 are directed to an invention not patentably distinct from claims 1-58 of commonly assigned application 11/535,003. Specifically, the claims are not patentably distinct for the reasons cited in the above obviousness type double patenting rejection.



The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/535,003, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

It is noted that the assignment data for the 11/535,038 and 11/535,003 application is not available to the examiner at this time. It is assumed that the instant application and the 11/535,038 and 11/535,003 applications are currently commonly owned. If this is incorrect, applicants are requested to inform the examiner of the current assignment data.

#### **Miscellaneous**

In Claim 117, applicants recite "selected from the group of (emphasis added) consisting of". Deletion of the first "of" would be remedial as inclusion of this word appears to be a typographical error.

Any rejections not repeated in this Office Action are withdrawn.


No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
January 17, 2008

  
DAVID GUZO  
PRIMARY EXAMINER